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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,519	02/28/2002	Jean-Christophe Audonnet	454313-2250.1	1340

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,519	AUDONNET ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-22* is/are pending in the application.

4a) Of the above claim(s) *16, 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-15 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims

1. Currently, claims 12-22 are pending in the application. Claims 16 and 17 have been withdrawn from consideration as being drawn to nonelected inventions. Claims 12-15, and 18-22 are pending in the application. Claims 12-15 and 18 were rejected in the prior action, mailed on June 3, 2003. In the Response filed on November 3, 2003, the Applicant amended claims 12, and 16-18, and added new claims 19-22.

Claim Objections

2. **(Prior Objection-Withdrawn)** Claim 12 was objected to in the prior action because of the following informalities: the claim refers to the bovine parainfluenza virus type 3 (BPIV-3) hemagglutinin/neuraminidase and fusion proteins by their respective letter abbreviations (HN and F) without first identifying the proteins by their full names. In view of the amendment to the claim, the objection is withdrawn.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. **(Prior Rejection-Maintained)** Claims 12-15, and 18 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 84-91, 93-95, 141-143, 149, and 150 of copending Application No. 09/760,574. In view of the addition of new claims 19-22, which read on structurally identical subject matter, the rejection is extended to these claims. The Applicant traverses the rejection on two grounds, neither of which is found persuasive.

First, the Applicant argues that the copending application does not render the presently claimed invention obvious. As the copending application claims overlapping subject matter to the present application (plasmid vaccines encoding the BPIV-3 HN and/or F proteins), it is not clear how the copending claims fail to render obvious the currently claimed invention which merely lacks the cationic lipids described in the copending claims. As the Applicant has merely asserted that the copending claims do not render the current claims obvious with no explanation as to why this is the case, the traversal is not found persuasive.

It is noted that the copending application is claiming a species of the genus of inventions claimed in the present application. It is accepted in patent law that a species anticipates a claimed genus. See e.g., MPEP 2131.02. However, since an anticipation rejection is not appropriate in a double patenting scenario, it is Office practice to reject the genus over the previously claimed species for obviousness type double patenting. See, MPEP § 806.04(i). Thus, the Applicant's

unsupported assertion that the copending application does not render obvious the present claims is not found persuasive.

The Applicant's second ground of traversal is the basis of the rejection, claims 141-143, and 149 have been withdrawn from consideration in the copending application, and may be cancelled therefrom. However, the claims have not been cancelled from that application. Thus, while the traversal would be persuasive if he claims had in fact been deleted, because this hypothetical situation has not yet arisen, the traversal on these grounds is not found persuasive. Because the claims forming the basis of the rejection are still pending in that application, withdrawal of the rejection is not warranted at this time.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. **(Prior Rejection- Maintained)** Claims 12-15, and 18 were rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Klippmark et al., J Gen Virol, 71:1577-80, in view of Suzu et al., Nuc Acids Res 15(7): 2945-58 (Genebank Accession Y00115), and further in view of the combined teachings of Felgner et al., WO 90/11092, and Crowe et al., Vaccine, 13(4): 415-21 (of record in the IDS filed on February 28, 2002). In this rejection, the above references are also considered in light of the teachings of Wathen et al., U.S. 5,169,628; and Babuik et al., Annals of the NY Academy of Sciences 772:47-63 (also of record in the February

28, 2002 IDS). In view of the addition of new claims 19-22, the rejection is extended to these claims. Thus, claims 12-15, and 18-22 are rejected over the references indicated above. The rejected claims read on immunogenic compositions against BPIV-3 comprising one or more plasmids encoding one or both of the HN and F proteins of the virus, and to methods of inducing immunological responses using the compositions.

The Applicant traverses this rejection on the grounds that those in the art would not have had a reasonable expectation of success in the combination of references as indicated by the Examiner. The Applicant supports this argument with the teachings of Morein, which teach that, although the HN and F proteins produced a protective response in mice, they did not produce such a response in lambs unless an adjuvant was added, and the declaration of Dr. Audonnet, which teaches that the administration of the claimed plasmids, apparently without adjuvant, were effective to raise an immune response. The Applicant concludes from this that the teachings in the art regarding the efficacy of the subunit vaccine in rodents would not provide adequate grounds for those in the art to expect that the HN and F proteins would induce a protective response in ruminants, and that because the applicants have established that such a response would occur, the invention is non-obvious However, the Examiner does not agree with the Applicant's interpretation of the teachings in the references.

As indicated in the prior action, Klippmark clearly teaches that the HN and F proteins of BPIV-3 are able to induce protective responses in animals. While, as Applicant indicates, the reference does not base this statement on the experiments of the authors of that reference, the teachings are nonetheless there.

Further, while the Morein reference teaches that the HN and F proteins were not alone capable of inducing a protective response in lambs, the reference teaches those in the art how to avoid the problem, i.e. by using an adjuvant. While Morein indicates that a composition comprising only the HN and F proteins (or plasmids encoding them) may not be effective vaccines in ruminants, by ignoring the additional teachings of Morein, the Applicant has misapplied the reference. I.e. those in the art would have been in possession of all of the teachings of the Morein reference, which include both the teachings regarding the problem, and those providing the solution to that problem (the use of an adjuvant). Thus, from the teachings of Morein, one of ordinary skill in the art would have known to include an adjuvant in a BPIV-3 vaccine using the HN and F proteins as antigens. It would therefore have been obvious to those in the art to also include adjuvants in the plasmid vaccines suggested by the other references cited by the Examiner. Because the claims use the "comprising" language in the transitional phrase of the claim, the current claims read on such compositions.

Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner

James C. Housel 1/24/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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